

European Commission - Pharmaceutical Sector Inquiry - Preliminary Report

(DG Competition Staff Working Paper, 28 Nov 2008)

PP01/09

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Comments

GENERAL REMARKS

- 1. The recent preliminary report on the pharmaceutical sector by DG Competition staff is of serious concern to members of this Federation, not merely those forming part of the pharmaceutical sector. The report makes assertions about the ways in which patents are legitimately used in all sectors of industry. As a Federation we do not support those who abuse a dominant position or who otherwise act in conflict with competition law. However, the tone of the report is that a whole sector of research based industry (which incidentally, according to a UK government scorecard carries out 26% of all private sector research in the UK) seeks to establish an unfair market.
- 2. Our comments will concern patent related matters, particularly those matters which affect a range of industry sectors. The regulatory framework for pharmaceuticals, including market authorisation, pricing and reimbursement, is mainly outside our competence.
- 3. It might be noted that the time allowed for comment on this long and complex report was very limited. When we have fully disentangled the many interlocking strands of data in the report, we may wish to comment again.

Innovation and patents

- 4. Innovation that provides new and improved products to meet human wants and needs is essential to a dynamic, competitive, forward looking society. The encouragement of innovative, research based, industry is crucial to the interests of all. Without innovation, our civilised society will stagnate. While universities and other public research institutions often achieve considerable success with basic research, they generally rely on the help of industry to translate the results into useful and commercially successful products. Organisations reliant on public funding would not have the capacity to carry out the extensive and practical research undertaken by innovative industry.
- 5. Remarkably, the encouragement of research based industry is provided by the patent system at very little cost to economic unions, state governments or individuals themselves. The relatively short term, limited periods of exclusivity provided by patents are generally sufficient to encourage innovative companies to devote the very considerable resources necessary to the conduct of research and development. Commercial companies are not philanthropic organisations they must make profits to reimburse their investors and to provide the livelihoods of their employees. There will be no profit in devoting large resources to innovation that can be freely and quickly imitated by non-innovative competitors. An exclusive market for a new



development, or an alternative benefit such as a royalty payment, is essential. Not only are profits necessary to meet the cost of successful innovation, but they must also meet the costs of large amounts of unsuccessful research and development, which almost inevitably must be undertaken before (and indeed after) success is attained. Not only do patents stimulate invention and acknowledge inventors, but they are essential business tools - without them, or if they are ineffective, there will be little innovation.

- 6. Innovation is essential to the success of modern civilised society, but no one should have a basic right to annex the products created by it. These products did not exist before the efforts of the innovator.
- 7. It is part of the patent system that a full disclosure of the invention to be protected has to be made in the application. This is published (if the application is European) 18 months after the priority date, which will usually be the date of the very first application anywhere in the world, thus providing much immediately useful and valuable information to others working in similar fields, stimulating competitive research from other innovators and, when the patents lapse or expire, enabling imitators to develop and produce equivalent products.
- 8. Patents are not incompatible with free competition. Patents do not stop research by others in the same or similar fields rather, patents provide much information, including the crucial information that something can be done. A lot of the disclosed information will not be protected by exclusive rights. Others may compete by providing alternative products, or by designing around what is protected, or may even negotiate a licence to make the protected product itself. The existence of the exclusive rights conferred by patents often encourages further innovation by others, all to the benefit of consumers. All that patents prohibit is direct imitation of a protected innovation that did not previously exist and even then the protection is only for a very limited time; very much less, for example, than the protection afforded by copyright in literary and artistic works. Weakening patent protection or limiting the ways in which innovators can use it is likely to cause some companies to rely more on keeping essential information secret as trade secrets, which would result in less information being available to others.
- 9. The report appears to take a rather negative attitude to patents and the use made of them by originator companies. It refers to a "toolkit" of procedures adopted by originator companies in order to protect their innovative products from imitation as though the use of this "toolkit" is somehow unfair. This is quite wrong. Indeed, four of the five components of the supposed "toolkit" patents, contact with infringers, litigation and settlement are intimately linked. Patents would be valueless if they could not be drawn to the attention of infringers, or litigated if the infringer took no notice, with litigation being resolved through settlement where possible. Discussion of the "toolkit" as though the so called tools are separate and it is somehow unethical or wrong to use them together (see e.g., paragraphs 890-894, 901-912) is thus very misleading.
- 10. Originator companies are entitled to protect their revenue streams, which are necessary to pay for past investment and to fund further research, by all legitimate means. The report should give attention to the pro-competitive and other benefits of patent systems. Patent systems may not be perfect, but no better way of encouraging innovation, especially at such little cost to the state, has ever been proposed.



Attitude of the report

- 11. Although the report does not clearly identify any illegal practices or infringement of EU competition rules, it appears to be critical of innovative, originator companies and in favour of imitators a position that we find surprising. One of the main aims of the EU should be to nurture and encourage innovative, research based companies but there is little indication of such an aim in this report. There seems to be no recognition in the report of the major contribution to human well-being made by the originator companies, or of the fact that the products they create would not exist without their efforts. While the report acknowledges the need to recoup investment costs (e.g., paragraph 365), the need of originator companies to make profits to support continuing research, much of which may be dead-end or in areas where profits will be very limited, is hardly acknowledged. This need seems to be regarded as being of relatively small importance when compared with the interests of imitators who of course would have nothing to copy without the efforts of the originators and who make large profits on the basis of the research, development and marketing done by others.
- 12. The report is inconsistent in its presentation of figures derived during the investigation and tends to shade the conclusions drawn from the information in a direction adverse to originator companies¹. Extreme figures, such as 1300 patents and applications protecting one blockbuster medicine (in 27 states), are quoted as though representative. While admitting that the pharmaceutical sector is already highly regulated, the report uses expressions such as "malfunctioning of the market" (paragraph 7) which give the impression that there is serious and widespread wrongdoing. Many of the figures quoted and from which large conclusions are drawn are small, especially considering that they refer to actions in 27 countries and apply to a large patent base. For example, detailed analysis of the outcomes of just 13 decided cases, as in paragraphs 1025-1027 is hardly warranted. As another example, divisional applications were filed in cases where the parent application was refused or withdrawn, over an 8 year period, by only a minority of originator companies (11 out of 43). The report does not indicate whether these were filed at the suggestion of the patent office and the numbers involved seem modest indeed (paragraph 400). Overall, the report is not a reliable basis for the formulation of future strategy.

¹ To give a few examples of a significant number of inconsistencies in the report:

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⁽i) Paragraph 393 says that the majority of litigated patents were revoked. This is not the case, as footnote 257 explains (27.5%).

⁽ii) Paragraph 893 says that generic companies win the vast majority of cases that are litigated. This is clearly not so. It appears from earlier data (e.g., paragraph 502) that the success rate is about 60%, in 149 decided cases from 698 litigations, i.e., about 13% of all litigations. Originators won more than half of the decided cases that they initiated (paragraph 504). Moreover, a "win" for a generic is frequently a declaration of non infringement, not an invalidation of the patent.

⁽iii) Paragraph 907 implies that 75% of patents are revoked following opposition. In fact, this figure covers patents that are amended as well as revoked.

⁽iv) As an example of shaded interpretation, paragraph 856 says that national authorities considered that the way originators used 2nd generation patents was part of a strategy to create obstacles, whereas the supportive quotation merely says that special strategies linked to patents can constitute barriers. [This is a statement of the obvious - the patents themselves should discourage unauthorised use]



- 13. Another disturbing feature of the report is that in a large number of instances remarks by originator companies concerning the need for the widest legitimate protection of the inventions involved in a new product or the lack of guarantee provided by a patent in advance of trial are quoted with the innuendo that they are indicative of wrong doing or anti-competitive behaviour (see e.g., paragraphs 386-390, 394-395,571). On the other hand, all remarks by imitator companies appear to be accepted at face value as indicative of dubious behaviour by originators. We reject such unbalanced use of the statements involved.
- 14. The report is suffused with the idea that the legitimate strategies of originator companies to maintain strong positions in the markets that they have created, such as drafting patent specifications with several examples and relatively broad claims, is somehow wrong (see e.g., paragraph 411).
- 15. The report says that the number of new active chemical entities currently reaching the market is smaller than in the past, implying that originator companies tend to rely on past success rather than keeping up efforts to develop new products. Research investment increases year by year, but the search for new breakthrough products becomes increasingly difficult as more and more research lines become exhausted. Meanwhile, the regulatory framework becomes more and more demanding as more is understood about safety risk factors. The increasing difficulties point to a need for research based industry to be given greater encouragement by the patent system, rather than less.
- 16. As regards research expenditure, the report makes a distinction between primary research and secondary development, as though the two are separable and that there is perhaps something less worthy of recognition in development work. The two areas are inextricably linked and without development and extensive trials, no invention would become a marketable new product.
- 17. It is made clear in the report that the only products of interest to imitators are the "block buster" high selling new products, which are of course the most important to originators. Without profits from these that can be devoted to research, not only to develop the product itself but also on different problems, there will be no improvement in the product or new products to help with less common conditions. Non-innovative companies have a valuable role in making available non protected, older products but are essentially free riders when taking advantage of the work of originators on new products. As the report makes clear, their aim is to market these at around 75-60% of the patent protected price (i.e., still a substantial proportion of the earlier price), even though they have done no research, no development, little testing and much less marketing. It would seem that non innovative companies are likely to achieve substantial profits while taking little risk.
- 18. When considering market features, the report several times draws attention to the fact that on average, originator companies spend more of their turnover on marketing and promotion (23%) than on research and development (17%), as though there were something reprehensible about this. All companies, whether innovative or not, must spend substantial sums on marketing and promotion, although product imitators need spend less than originators, since demand for the product has already been established. If commercial companies did not spend substantial amounts on promotion and marketing, they would sell little and new and beneficial products would not reach the market. On the other hand, only a small proportion of all



- commercial companies spend significant sums on research and development. The two areas of marketing and research are not related.
- 19. As a significant aspect of the market, the report suggests that on average there is about 7 months between loss of exclusivity by an originator company and the entry of an equivalent product into the market. The report is unclear about the causes of such delay, and it should not be attributed to the patent system or the behaviour of originator companies. It is noteworthy that the delay is less than average for blockbuster medicines, which suggests unsurprisingly that imitators will make greater efforts to reach the market quickly when the anticipated profit is greater, i.e., the delay is inversely as the value of the particular market to be entered. A modest delay is to be expected in most fields, not just the pharmaceutical (and 7 months seems rather modest, especially when compared with the time that the originator company will have spent in reaching the market 8.6 years according to paragraph 121), since competing imitative producers must finalise their clearances, develop the manufacturing capacity and enter the market.
- 20. The report appears to rely to a considerable extent on the views of imitators. It appears that a large part of the report is drawn up from their point of view (see paragraph 8, 1) and much of the criticism of the patent system appears to stem from them. A recent commentary by this Federation in response to a review of alleged weaknesses in the European patent system by the European Generic Medicines Association in the early part of last year is therefore attached.

PATENT FILING STRATEGIES

- 21. The report appears to take exception to the normal approach to patent drafting, used across all industries. Paragraph 411 quotes with implied disapproval (in the context of the preceding paragraph) an originator's effort to draft with sufficient examples supporting sufficiently broad claims to deter imitative competitors. This is the very essence of drafting a patent specification, keeping in mind that the law requires that the claims should be supported by what is described.
- 22. While appearing to acknowledge that most developments involve a number of incremental steps, some or all of which might involve inventions, the report takes a highly critical line as regards so called "follow-on" or "secondary" patents and patent "clusters" or "thickets". It takes an unfavourable attitude to the protection of "second generation" medicines.
- 23. It is not to be expected that all aspects of a line of research and development can be covered by a few patents, in the pharmaceutical or any other field. A line of research may take many years to perfect, following the grant of early patents. Many variants, improvements and modifications may be tried out. Thus most inventions are protected by clusters of patents a small number of patents will often prove to be ineffective for protecting an inventive concept, since as understanding develops, potential imitators will soon find ways round them. In chemical fields, several series of potentially similar compounds will be investigated and protected as far as possible, against the possibility that the lead compound fails at some stage. There is nothing wrong in seeking an optimal competitive position (paragraph 413).
- 24. This is so in many industries and indeed is readily acknowledged and a source of pride -manufacturers in the vehicle and domestic appliance industries for example mention



the large numbers of patents that they hold in order to protect their inventions, in their advertising materials.

- 25. Moreover, it is not surprising that there should be a steady rise in patent applications throughout the useful life of a product. In the pharmaceutical field for example, there will be efforts to improve the therapeutic effect, reduce side effects, improve methods of delivery to the patient and so on. If these improvements involve invention that meets patentability requirements, they are entitled to patent protection. Such developments and improvements can be significant advances. The Federation is fundamentally opposed to special rules for, or discrimination against, patent applications on the basis that they are somehow secondary, whether in the pharmaceutical or any other sector. Applications that meet the legal requirements of novelty, inventive step and industrial applicability (i.e., patentability) and sufficiency of disclosure should not be denied grant. The patent system should not be biased against related patents. The patents follow the research, not vice-versa.
- 26. Patents and patent families that are not to be commercialised and do not afford protection for the marketed products tend to be abandoned in view of the escalating costs of renewal fees in the later years of patent life, thus making the technology available to all.
- 27. The pejorative use of terms in the report such as 'cluster', 'thicket', 'follow-on', 'secondary' and 'evergreening' is unfortunate and undesirable. These terms are of course used by imitators to downplay the worth of the inventions and related patents involved. The test of validity for every patent is and should be the same does the invention which is the subject of the patent application meet the normal requirements of patentability and sufficiency?
- 28. The report alleges that related patents cause complications and delays for imitators. They do not do that. Products within the scope of a lapsed or expired patent, e.g., a first generation product, and not including new features protected by a later one can be made by imitators newer patents do not re-protect the inventions covered by expired patents. The rule is simple and there should be no legal uncertainty. Imitators can copy that which is not protected because the patent has lapsed or expired, but should not copy that which is protected by a patent in force.
- 29. If the later generation products show little or no significant advantages, there should still be a substantial market for the first generation, as the report concedes at paragraph 861. If there is no such market, the fault does not lie with the patent system but may well lie with the imitator companies who rely on the marketing efforts of the originator rather than their own. To suggest, as the imitators apparently do, that switching from a first to a second generation product, when there is little advantage in the second generation, will mean that there can be no further switching to a much less expensive equivalent produced by the imitator is a feeble argument and perhaps indicates a lack of marketing effort. Our member companies report that so called second generation patents do not deter imitator companies.
- 30. The report is critical of the fact that some applicants, on occasion, divide their patent applications. (As noted earlier, the numbers involved are relatively small.) The division of an application disclosing more than one invention into new applications is perfectly legitimate and is often required by patent offices. Situations where the original parent application is refused or withdrawn and the divided application pursued can be those where the direction of development has changed.



The divided application is of course in respect of a different invention and is entitled to be properly considered on its own merits, not those of the parent. Division does not result in any change of priority date from that of the original application and all information about the inventions will have been made available in the application(s) when published 18 months from the priority date. A consequence of division may sometimes be a lengthened period between application and grant, though this time is often prolonged by patent office delays, rather than being caused by applicants, who may be anxious to enforce the patent. However, the overall term of protection will not extend beyond that afforded by the parent application. As for all patents, it is necessary to await the granted patent to assess the scope of protection. The patent office concerned has control of the process and sets the time limits to be observed by applicants, so whether or not patents are granted quickly is very much in its hands. The scope for improving procedures in the EPO without loss of quality should be examined. In the UK for example, all patents, divided or not, must be put in order for grant within the same predetermined time period. However, it can hardly be argued that an imitator company is delayed in reaching the market by such a patent. The obvious intention must be to imitate what is disclosed, so the underlying assumption should be that this can be done when the patent expires, not before it is granted.

- 31. The report suggests that later patents are frequently "weak". Presumably this means that they are likely to be invalid. What is much more likely is that later patents will be quite narrow, as being concerned with improvements in the particular product, process or use concerned. The implication that applicants deliberately file applications of unsatisfactory quality on a considerable scale is misconceived. Applicants will necessarily prepare applications in a responsible way, since they will have to maintain and defend the granted patent in the future. It is the duty of the patent office (the EPO in most cases in the field under consideration) to confirm that the application complies with the legal requirements to sufficiently describe and claim a patentable invention.
- 32. The EPO and several national patent offices within the EU are recognised internationally as granting strong patents with a high presumption of validity. It is noteworthy that the report indicates that of those pharmaceutical cases where the office had reached a final decision on whether the patent should be granted, only 34% were granted (paragraph 346). This does not suggest that it is easy to secure such patents through the EPO. If, infrequently, potentially invalid patents are granted, they can be challenged through opposition and revocation procedures.

LITIGATION

33. The report recognises that originators may legitimately enforce their patents in court, but gives the impression that this is somehow reprehensible. Bearing in mind the importance of patents, particularly to the innovative pharmaceutical industry, in protecting research and development expenditure in fields where inventions can be very easily imitated from the disclosures in published patent specifications, it is not surprising that there is a significant amount of litigation. No company enters upon litigation lightly since it involves the considerable use of specialised technical and legal resources that would be much better employed elsewhere. For a company to take infringement action against imitators demonstrates confidence in the underlying



- patents. Neither is it surprising that litigation may be initiated in several EU member states, since the patents concerned have only national (single state) effect.
- 34. The general wish of health authorities, and indeed the general public attitude, is to encourage generic substitution. This will inevitably, although it should not, influence judicial attitudes. Moreover, considerable numbers of patents are not infringed on a substantial scale and are not therefore litigated. With many other patents, the scope of the invention and whether the patent has been infringed are very clear, so that the parties do not resort to litigation. Litigation usually involves situations where there is some uncertainty concerning the scope of the patent and of the alleged infringement or the validity of the patent to resolve, so it is not surprising that success rates of originator companies are relatively modest. Indeed, the alleged 60/40 split in favour of the imitator companies is probably a better outcome for patent owners in the pharmaceutical field than for those in many other fields.
- 35. The report fails to mention or explore the consequences of tactics that can introduce significant delays and are often adopted by imitator companies when faced with an infringement action, e.g., seeking a declaration of non infringement in another court that is expected to be very slow, so that the main action will be suspended.

INTERIM INJUNCTIONS

- 36. It is inevitable that patent owners whose businesses are being damaged by imitators will seek injunctions this is so in all industries. All jurisdictions are reluctant to grant interim injunctions pre trial and make considerable efforts to balance fairly the competing interests, so the 50% success rate, as given in the report, in securing these probably indicates that the courts take a generally positive view of the patents involved and that the originators' businesses will be severely affected if they are not granted. However, the figures given are not very informative because they do not indicate how the infringement allegations involved fared at subsequent trial. And it should be noted that originator companies who secure interim injunctions but lose at trial will have to pay substantial compensation, so that there is a strong disincentive to seeking injunctions if the underlying patent is suspect.
- 37. Interim injunctions are orders to desist from an infringement of a patent in force, so they should not be regarded as delaying market entry. If the imitator had respected the patent in the first place, he would not be trying to enter the relevant market before the patent has expired. Imitators who succeed at trial will receive compensation for any delay caused by an invalid or non infringed patent.

OPPOSITIONS AND APPEALS

38. The report notes that the time taken to settle oppositions limits the ability of imitator companies to clarify the patent situation. Lengthy delays can also limit the patent owner's opportunities for early enforcement. The clarification sought by the imitator is of course to determine how much of the invention involved can be imitated immediately, rather then when the patent expires normally. An opposition before the EPO can take a considerable time to settle, since both parties must be given fair opportunities to present their arguments, as in any litigation, but we agree that EPO procedures should be examined in an effort to streamline the process, without loss of quality. However, it is likely that it will be completed, together with



- any subsequent appeal, many years before the expiry date of the patent concerned. Moreover, as the report indicates, opponents that are particularly concerned to secure an early decision can launch actions for revocation in the member states.
- 39. The report suggests that imitator companies "prevailed" in 75% of final decisions, but the figure for revoked patents is substantially lower (59%). This figure gives no indication as to the likely validity of the great majority of patents. Oppositions will only be launched when there is a fair prospect of success. In a significant number of cases, patents are amended as a result of opposition. This may not represent a particular success for the opponent. It might be more meaningful to indicate the proportion of all pharmaceutical patents that are actually opposed and the proportion of those that proceed to a final decision.

SETTLEMENTS AND AGREEMENTS

- 40. The report notes that there have been considerable numbers of settlements to resolve patent disputes as well as numerous other agreements. In any agreement, EU competition law must be complied with. We consider that generally, the willingness of parties to settle before the completion of trials should be regarded as beneficial. Settlements are certainly encouraged by the courts and are normal in all technical fields. Settlements and agreements that facilitate market entry to imitator companies, even when subject to conditions, should be welcomed, because they will increase competition and market place choice.
- 41. In more than half of settlements referred to in the report, there were no restrictions on generic market entry, while in many others, and in other agreements, licences were granted. Licence conditions must comply with EU competition policy. Fair conditions are block exempted from EU reporting rules. Thus the conclusion in paragraph 894 that settlements limit generic entry is disturbing. The willingness of imitator companies to accept licences with conditions indicates a respect for the underlying patent and a realisation that the licence will enable them to reach the market earlier, not later, than would otherwise be the case. Licences should not be considered as problematic licence arrangements should improve availability and choice to consumers. Neither should payments to imitators e.g., to compensate them for products transferred to the innovator or for time lost due to an interlocutory injunction, be treated as suspicious. As the report concedes (paragraph 663), each individual agreement would require an in depth analysis to determine its compliance with EU law and its contribution to increased competition.

DEFENSIVE PATENTS; R & D PROGRAMMES

42. The term "defensive patent" is defined in the report as a patent that is not to be used to protect the inventions of the innovator but to block the development of competing products (paragraph 959). It is of course part of the patent system that patents are awarded for inventions of the inventor (innovator/originator) and that they should be used. From the replies received, it does not seem that many of the responding companies fully understood the term as used in the report. The great majority, if not all, patents in all fields, might be described as defensive, since the purpose of the patent system is to give the right to stop others using the invention that the originator has made. The report alleges that so called defensive patents are obstacles to innovation and results in higher costs to competitors, because of royalty

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payments. The report also comments more generally on the potential blocking of research activities by competitor patents and suggests that this is detrimental to the innovation process

- 43. It is not clear that there is any evidence that deliberate blocking is a common practice indeed, the report refers to only one example of research being blocked by a patent. Nevertheless, applying for a patent at the earliest opportunity is a legitimate, indeed essential feature of the patent system. What will be blocked is a later development of the same invention, giving the competitive edge to the first inventor to file in respect of a given invention. The need for research to take account of the existing patents and activities of competitors is a general issue for all research based companies, not merely those in the pharmaceutical sector
- 44. This is an essential component of a competition based market, shown by studies and experience to stimulate rather than discourage invention. Far from discouraging innovation, strong patent systems are an important feature of societies that encourage innovation, competition and economic activity. Innovation delivers lower costs and a wide variety of high quality goods to consumers.
- 45. The report even alleges that the publication of information blocks competition (paragraph 971). This is a remarkable suggestion. In the absence of a patent, competitors are free to make and market what is disclosed in the publication. Moreover, any such publication contributes to the available knowledge base. Competitors can use the knowledge base for their own research and development.
- 46. Competitors who fall behind should tackle other problems, or approach the same problem in different ways, e.g., by by-passing the patents concerned, or seek licences on patented technology that might be needed. The royalties involved are not an added burden but a fair payment for the use of another's invention.

COMMUNITY PATENTS AND EU WIDE JURISDICTION

- 47. We agree that a properly constructed Community patent system is a desirable EU objective that should enable a single patent having uniform effect throughout the EU to be secured and maintained. This should be at much lower cost than that of the bundle of separate national patents currently available through either the European or national patent systems. However, it should be recognised that the Community patent will not of itself alter the standard of patent examination in the EPO or change the "strength" of patents The Community patent will be subject to the same examination and opposition procedures, to the same standards, as the current European patent.
- 48. Also, we support the introduction of a carefully considered and effective EU wide patent jurisdiction which simplifies the problems of EU wide patent litigation. However, this will only be effective and trustworthy if there is a highly competent and expert patent judiciary, operating to clear and satisfactory procedures, otherwise the problems will be greater than they are now. The proposals currently under discussion are a long way from meeting the essential requirements. Our recent position paper on this subject indicates the problems in detail (attached).



CONCLUSIONS

- 49. Innovative companies are the life blood of the EU. They should be encouraged, not attacked. The report demonstrates that there is a hostile attitude in the EU towards enterprising, risk taking innovators.
- 50. Any patent application for an invention which meets the legal requirements of novelty, inventive step and industrial applicability (i.e., patentability) and includes a sufficient disclosure should be eligible for grant.
- 51. It is legitimate to protect inventive improvements in patented products with further patents.
- 52. Standards for patent grant in the EPO are internationally acceptable, though procedures might be improved and delays reduced.
- 53. It is legitimate to use patents to secure market exclusivity, by litigation if necessary.

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